

REMARKS AND ARGUMENTS

After entry of this amendment claims 83-99 and 113-119 are pending. Support for the amended and new claims is found throughout the disclosure with exemplary support as follows.

5

Claim	Specification support
83	page 266, lines 1-2 - exemplary lipid disorders
87	page 111, line 9 through page 112, line 12 - chemical structure
113-117	pages 55-57, 71-89 - chemical structures and variable group substituents
118-119	page 169, line 5 et seq. - formulations

10

15

35 U.S.C. § 102(a)

The Office rejected claims 83-99 under 35 U.S.C. § 102(a) as anticipated in view of Dowell et al. U.S. patent No. 5,859,000, of record (hereafter Dowell).

Amended claim 83 recites treatment of subjects having the listed conditions and the rejection should be moot. The prior version of claim 83 recited treatment of subjects that had or were subject to developing the claimed conditions.

20

35 U.S.C. § 103(a)

The Office rejected claims 83-99 under 35 U.S.C. § 103(a) obvious in view of Dowell. The rejection should be moot in view of the amendment to claim 83 as discussed above.

25

35 U.S.C. § 112, first paragraph

The Office rejected claims 83-99 under 35 U.S.C. § 112, first paragraph because the term "lipid disorder" was unclear. Claim 83 is amended to replace that term with specific lipid disorders, and this ground for the rejection should be moot.

30

35 U.S.C. § 112, first paragraph

The Office alleged that the specification failed to provide any guidance on how to use the claimed compounds by failing to provide effective dosages or modes of administration. Applicants traverse this ground for the rejection. The Office's attention is directed to, e.g., page 169, line 5 through page 178, line 12, which provides detailed description of formulations and modes of administration, and page 178, line 13 through page 179, line 4, which provides detailed description of dosages. Other relevant teaching is elsewhere in the disclosure. Given the disclosure's detailed teaching, Applicants submit that the disclosure properly enables modes of administration and dosages for the claimed compounds.

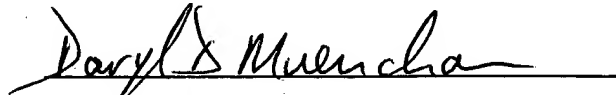
The Office alleged that the disclosure did not contain sufficient evidence to support the practice of claimed treatment methods without undue experimentation. The Office's attention is directed to the declaration that accompanies this response. The declaration points out that human clinical trials show that the compound $3\beta,7\beta,17\beta$ -trihydroxyandrost-5-ene has activity in reducing elevated cholesterol and triglyceride levels, while increasing the cholesterol:HDL ratio. This data is consistent with the disclosure's teaching at, e.g., page 258, lines 9-14, which disclose the use of the compounds in obesity or diabetes conditions to reduce low density lipoprotein, triglyceride, cholesterol or serum apoB levels. Obesity and diabetes are often associated with the onset or progression of conditions such as arteriosclerosis and elevated cholesterol. See, e.g., *The Merck Manual of Diagnosis and Therapy*, 17th ed., M.H. Beers et al., eds., chapter 201, pgs. 1654-1658, newly cited, H.C. McGill et al., *Circulation* 105:2712-2718, 2002, newly cited. Given the objective evidence of activity by $3\beta,7\beta,17\beta$ -trihydroxyandrost-5-ene, Applicants submit that the claimed methods are enabled. The accompanying data and the specification's detailed teaching of how to use the compounds are objective evidence of efficacy for the claimed methods. Applicant's disclosure provides detailed teaching of how to practice the claimed methods without undue experimentation, which is evidence of sufficient enablement for the claimed methods.

Applicants request reconsideration and withdrawal of the rejection.

HOLLIS-EDEN PHARMACEUTICALS, INC.

5

Dated: 11-9-04



10

Daryl D. Muenchau, Reg. No. 36,616
Hollis-Eden Pharmaceuticals, Inc.
4435 Eastgate Mall, Suite 400
San Diego, CA 92121
Phone: 858-320-2569
Fax: 858-558-6470

15